510(k) Summary

Product Name: Mammography Prior Enhancement (MPE)

DEC 2 0 2012

Product Classification Name: Picture archiving and communication system

Product Classification Code: LLZ **CFR Section:** 892.2050

Classification Panel: Radiology **Class** II

Manufacturer: Hologic, Inc.
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Bedford, MA 01730 USA

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Date Prepared: November 13, 2012

Predicate Device: Digital Now HD K091368

Predicate Device Description:

The Digital Now HD, K091368, is a software application intended to process digitized screen film mammography images for comparison purposes only. The software processes digitized prior film images to produce lossy-compressed DICOM images that more closely resemble digital mammography images. The R2 DigitalNow HD images are intended for comparison purposes only and cannot be used for primary diagnosis. The DigitalNow HD is a software application which runs on the Hologic Cenova server. (Class I exempt per 21 CFR § 892.2010 and CFR § 892.2020).

Device Description:

MPE is a software application that runs on a Windows server or softcopy display workstation, such as SecurView DX (K103385). MPE processes (manipulates) prior GE digital mammography images so that they will appear similar to Hologic digital mammography images. The image processing consists of various steps to improve visualization of structures in the breast including, logarithmic conversion, skin line correction and contrast enhancement. These are standard methods used to allow optimal display and review of mammography images with minimal window/leveling operation.

Intended Use:

Mammography Prior Enhancement (MPE) is a software application intended to enhance the appearance of prior non-Hologic digital mammography x-ray images so that they more

closely resemble Hologic digital mammography images. MPE processed images are intended for comparison purposes only and cannot be used for primary diagnosis.

MPE runs on a Windows-based computer. Results can be displayed on a workstation capable of displaying mammography x-ray images, such as Hologic's SecurView® DX workstation, Product Code LLZ, CFR 892.2050 (K103385)

Comparison with Predicate Device:

The MPE software application is similar to DigitalNow HD cleared as K091368. Both devices are software sharing the same technological characteristics. MPE and Digital-Now HD are both used to further process mammography images for use as reference during prior to current mammography image comparisons.

Technological Characteristics:

The device is software application and does not contact the patient, a diagnosis is not made from the MPE processed image, nor does it control any life-sustaining devices.

Safety and Effectiveness Concerns:

MPE is designed and manufactured in accordance with the following standards:

- ISO 13845 Medical Devices – Quality management Systems
- ISO 14971 Medical Devices – Application of Risk Management
- IEC 62304 Medical Device Software Life Cycle Process
- 21 CFR Part 820 – Quality System Regulations

The performance of the software is tested in accordance with Hologic's design control procedures to demonstrate intended performance. Potential hazards are controlled via risk management processes and verification and validation testing. Instructions for use are provided to facilitate intended operation.

Conclusion:

The MPE software further processes and displays prior digital mammography images for physicians or trained medical personnel to use as a historical image reference when reviewing current Hologic digital mammography images. The MPE processed images will appear similar to Hologic digital images.

The MPE software application and the predicate device share the same intended use, technical characteristic and performance standards. Potential hazards have been studied and controlled by a Risk Management Plan. Device failures which might result in partial or failed images do not affect the original saved image so there is no risk of data loss. MPE processed images are not intended for diagnosis. Based on the information supplied in this 510(k), the MPE software application is safe, effective and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 20, 2012

Ms. Gail Yaeker-Daunis
Senior Regulatory Affairs Specialist
Hologic, Inc
36 Apple Ridge Road
DANBURY CT 06810

Re: K123530
Trade/Device Name: Mammography Prior Enhancement
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 15, 2012
Received: November 26, 2012

Dear Ms. Yaeker-Daunis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris -S

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123530

Device Name: Mammography Prior Enhancement

Indications for Use:

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MPE runs on a Windows-based computer. Results can be displayed on a workstation capable of displaying mammography x-ray images, such as Hologic's SecurView® DX workstation.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Janine M. Morris -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123530